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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : G06F 19/00, 15/80 // 159:00	A3	(11) International Publication Number: WO 97/29447 (43) International Publication Date: 14 August 1997 (14.08.97)
(21) International Application Number: PCT/US97/02104 (22) International Filing Date: 7 February 1997 (07.02.97) (30) Priority Data: 08/599,275 9 February 1996 (09.02.96) US 60/011,449 9 February 1996 (09.02.96) US (71) Applicant (for all designated States except US): ADEZA BIOMEDICAL CORPORATION [US/US]; 1240 Elko Drive, Sunnyvale, CA 94089 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): LAPOINTE, Jerome [US/US]; 3051 Revere Avenue, Oakland, CA 94605 (US). DESIENO, Duane, D. [US/US]; 2015 Olite Court, La Jolla, CA 92037 (US). (74) Agent: SEIDMAN, Stephanie, L.; Brown Martin Haller & McClain, 1660 Union Street, San Diego, CA 92101-2926 (US).	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> (88) Date of publication of the international search report: 7 May 1998 (07.05.98)	
(54) Title: METHOD FOR SELECTING MEDICAL AND BIOCHEMICAL DIAGNOSTIC TESTS USING NEURAL NETWORK-RELATED APPLICATIONS (57) Abstract Methods are provided for developing medical diagnostic tests using decision-support systems, such as neural networks. Patient data or information, typically patient history or clinical data, are analyzed by the decision-support systems to identify important or relevant variables and decision-support systems are trained on the patient data. Patient data are augmented by biochemical test data, or results, where available, to refine performance. The resulting decision-support systems are employed to evaluate specific observation values and test results, to guide the development of biochemical or other diagnostic tests, to assess a course of treatment, to identify new diagnostic tests and disease markers, to identify useful therapies, and to provide the decision-support functionality for the test. Methods for identification of important input variables for medical diagnostic tests for use in training the decision-support systems to guide the development of the tests, for improving the sensitivity and specificity of such tests, and for selecting diagnostic tests that improve overall diagnosis of, or potential for, a disease state and that permit the effectiveness of a selected therapeutic protocol to be assessed are provided. The methods for identification can be applied in any field in which statistics are used to determine outcomes. A method for evaluating the effectiveness of any given diagnostic test is also provided.		

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INTERNATIONAL SEARCH REPORT

In national Application No
PCT/US 97/02104

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G06F19/00 G06F15/80 //G06F159:00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	MONETA C ET AL: "AUTOMATED DIAGNOSIS AND DISEASE CHARACTERIZATION USING NEURAL NETWORK ANALYSIS" 18 October 1992, EMERGENT INNOVATIONS ON INFORMATION TRANSFER PROCESSING AND DECISION MAKING, CHICAGO, OCT. 18 - 21, 1992, VOL. 1 OF 2, PAGE(S) 123 - 128, INSTITUTE OF ELECTRICAL AND ELECTRONICS ENGINEERS XP000366477 see page 123, column 2, line 15 - line 25 see page 125, column 1, line 2 - page 126, column 1, line 24 ---	1-145
A	WO 94 25933 A (PAVILION TECH INC) 10 November 1994 see page 4, line 1-18 see page 16, line 22 - page 17; table 1 --- -/--	1,9,24, 97,121

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

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- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search

20 January 1998

Date of mailing of the international search report

20.02.98

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INTERNATIONAL SEARCH REPORT

In International Application No
PCT/US 97/02104

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>BAXT ET AL: "bootstrapping confidence intervals for clinical input variable effects in a network trained to identify the presence of acute myocardial infarction" NEURAL COMPUTATION, vol. 7, 1995, 624-638, XP000675029 cited in the application see the whole document ---</p>	1-145
A	<p>NEJAD ET AL: "significance measures and data dependency in classification methods" 1995 IEEE INTERNATIONAL CONFERENCE ON NEURAL NETWORKS PROCEEDINGS, AUSTRALIA, pages 1816-1822, XP002037553 see page 1817, column 1, line 26 - page 1819, column 2, line 17 ---</p>	1,9,24, 97,121
A	<p>BENEDIKTSSON ET AL: "parallel consensual neural networks with optimally weighted output" PROCEEDINGS OF WORLD CONGRESS ON NEURAL NETWORKS , vol. 3, 5 June 1994, SAN DIEGO CA US, pages 129-137, XP002052712 see page 130 - page 133, line 26; figures 1,2 ---</p>	164
A	<p>KIM ET AL: "ensemble competitive learning neural networks with reduced input dimension" INTERNATIONAL JOURNAL OF NEURAL SYSTEMS, vol. 6, no. 2, June 1995, SINGAPORE, pages 133-142, XP002052713 see page 135 - page 136; figure 1 ---</p>	164
A	<p>US 5 463 548 A (ASADA ET AL) 31 October 1995 -----</p>	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 97/02104

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see annexed sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☒ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/ US 97/02104

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims 1-145 : A method for identifying and selection of important variables that aid in the diagnosis of disorders or conditions.
2. Claims 146-163: A method for diagnosing endometriosis.
3. Claims 164-169 and partially the claims 148-150, 153,156-159, 162-163: A neural network system to aid in the diagnosis of endometriosis.

INTERNATIONAL SEARCH REPORT

Information on patent family members

In tional Application No

PCT/US 97/02104

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9425933 A	10-11-94	AU 6669594 A	21-11-94
		CA 2161655 A	10-11-94
		EP 0696372 A	14-02-96

US 5463548 A	31-10-95	US 5622171 A	22-04-97
